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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/067,097	02/04/2002	Frederick J. Foley	1005-009US01	4313

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EXAMINER

VENIAMINOV, NIKITA R

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 08/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/067,097

Applicant(s)

FOLEY, FREDERICK J.

Examiner

Nikita R Veniaminov

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 12-24 and 26 is/are rejected.
- 7) ☒ Claim(s) 5-11 and 25 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

DETAILED ACTION

Claim Objections

1. Claim 11 is objected to because of the following informalities: The phrase "from" before the phrase "device" in line 2 should be deleted. Appropriate correction is required.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 12-20 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. With regard to claim 12 by using the phrases "device that contacts an organ" in line 2, and "device that extends around a substantial volume of the organ" in line 3 Applicant appears to claim a living body part as an element of the apparatus. The phrases should read: "device that is adapted to contact an organ" and "device that is adapted to extend around a substantial volume of the organ" to avoid these problems. Appropriate correction requested.

Claim R jections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. By using the phrase "wherein adhering" in line 1 it is unclear if Applicant refers to one of the previously defined method steps. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-4, 12, 14, 17-19 and 21-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Anstadt (US 5,119,804). Anstadt ('804) teaches an apparatus comprising a manipulating device that is adapted to contact an organ [see column 4, lines 46-56 and Figure 4(30 and 50)]; a bag-like device that is adapted to extend around a substantial volume of the organ and the manipulating device (see Figure 4(20) and column 4, lines 46-48), said bag-like device, which

is formed from a flexible polymer (see column 5, lines 6-29), further comprising a center region that engages the manipulating device [see Figures 4(70) and 10(70)], and a support shaft, which is a vacuum tube, coupled to the manipulating device [see Figure 3(160, 150 and 155)]. Further, Anstadt ('804) teaches a method comprising engaging a manipulating device with the apex of the heart to define a chamber [see Figure 1(20 and 80)]; applying vacuum pressure to the chamber such that a portion of the manipulating device deforms to substantially seal the chamber against leakage [see column 7, lines 3-11; Figure 3(150, 155 and 160) and Figure 8(50)]; deploying said bag-like device around at least a portion to the heart; manipulating, supporting or securing the heart with the bag-like device (see Figures 1, 3 and column 7, lines 3-24).

8. Claims 12-17, 21, 23, 24 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Cox et al. ('706) cited by Applicant. Cox et al. ('706) teach an apparatus comprising a manipulating device that is adapted to contact an organ (see Figure 1(20, 22) and column 6, lines 4-13); a bag-like device that adapted to extend around a substantial volume of the organ and the manipulating device (see column 5, lines 52-67 and Figure 3); said bag-like device comprising a pliable net which is formed from a flexible polymer having a center region that engages the manipulating device (see Figures 1(12) and 3); a netting defining mesh apertures (see Figure 3 and column 7, lines 31-37); a perimeter; the perimeter comprising a pliable netting and a drawstring (see Figure 3 and column 7, lines 21-30). Further, Cox et al. ('706) teach a method comprising engaging

an organ with a manipulating device (see column 8, lines 15-30); deploying a bag-like device around a substantial volume of the organ; and manipulating (supporting, lifting) the organ with the manipulating device and the bag-like device (see column 8, lines 15-58); securing the bag-like device around the organ (see column 7, lines 43-47); and cutting the bag-like device (see Figure 3).

Allowable Subject Matter

9. The following is a statement of reasons for the indication of allowable subject matter: Anstadt ('804) and Cox et al. ('706) teach a manipulation device that is adapted to contact an organ; a bag-like device adapted to extend around a substantial volume of the organ and the manipulating device; and a method of using said apparatus described in paragraphs 7 and 8 above. Buckman, Jr. et al. (US 5,571,074) teach a heart massager for substernal heart massage comprising a heart-contacting surface. The ends of a cup are joined by a flexible sidewall; the cup's flexible sidewall allows a heart-contacting member to collapse so that it can be inserted into a relatively small incision in the chest cavity. After the heart-contacting member is inserted, fluid pressure is applied to an inside of the cup, thereby causing it to expand into its operative state (see abstract). Melvin (US 5,957,977) teaches an activator device for activation of cardiac tissue having a stint for placement within the interior volume of a natural heart adjacent cardiac tissue thereof; a yoke for placement around a portion of the exterior surface of the natural heart in general alignment with the stint and connected to the stint by

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at least one cord (see abstract and Figures 2, 5A and 5B). However, none of the prior art, either alone or in combination, teaches or suggests a bag-like device comprising an aperture sized to permit passage of a support shaft and sized to block passage of a manipulating device. Also, none of the prior art, either alone or in combination, teaches or suggests a method comprising engaging a manipulating device with the apex of the heart to define a chamber; applying vacuum pressure to the chamber; deploying the bag-like device around the heart by unrolling the bag-like device that further includes either securing a deployed bag-like device around the heart by pulling a drawstring; threading a vacuum tube through an aperture in the bag-like device and applying vacuum pressure to the chamber through the vacuum tube or cutting the bag-like device to expose a region of the heart or to remove the bag-like device from around the heart.

10. Claims 5-11 and 25 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Melvin ('977); Buckman, Jr. et al. ('074); Benetti et al. ('569); Kovacs ('839); Kovacs et al. ('627); Alferness ('343); Adelman et al. ('314); Grooters ('905); Snyders ('132); Goetz ('990) and Ellman ('375).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikita R Veniaminov whose telephone number is (703) 605-0210. The examiner can normally be reached on Monday-Friday 8 A.M.-5 P.M..


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eric F Winakur can be reached on (703) 308-3940. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0758 for regular communications and (703) 308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Nikita R Veniaminov
Examiner
Art Unit 3736

July 30, 2003.



ERIC F. WINAKUR
PRIMARY EXAMINER